REMARK

Applicant intends this response to be a complete response to the Examiner's **16 January 2007** Non-Final Office Action. Applicant has labeled the paragraphs in his response to correspond to the paragraph labeling in the Office Action for the convenience of the Examiner.

DETAILED ACTION

1. Application 09765061, (20030022165 Al): Claims 1-27 are pending. Claims 1-8, 14-20, 25 and 26 are withdrawn from consideration. Claims 9-13, 21-24 and 27 are examined.

Election/Restrictions

2. This application contains claims 1-8, 14-20, 25 and 26 drawn to an invention nonelected with traverse in the Paper entered 7/6/2006.

The Examiner Contends as follows:

> A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See **MPEP § 821.01.**
>
> Applicants have so amended the claims.

Priority

3. This application, 09/765,061, was filed 1/17/2001.

The Examiner Contends as follows:

> 4. The examiner respectfully submits that the application does not satisfy the requirements for 35 U.S.C. 119(e) benefit.
>
> If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-inpart) of the applications.
>
> If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by

35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR .1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Benefit to Serial No. 60/331362

5. The examiner respectfully notes that the image file wrapper shows a preliminary amendment, filed 5/2/2002, which amends the Specification at p. 1, lines 5-7, from stating "set bearing Express Mail Label EL 389 348 319 US to the United States Patent and Trademark Office" to --Serial No. 60/331362 filed--. The effect of this proposed amendment would be to change the specification, as filed, to clearly claim of benefit of Serial No. 60/331362, filed 1/4/2001.

However, a Notice of Non-Compliant Amendment, mailed 7/1/2002, found that a clean version of the entire page showing changes, had not been furnished, as required. Because applicant has not provided the required clean version, the examiner does not consider that a perfected claim to benefit of provisional application Serial No. 60/33162, filed Jan. 4, 2001, has been made. Therefore, benefit of Serial No. 60/331362, filed Jan. 4, 2001, is not granted to the instant application.

The examiner respectfully acknowledges the Decision on Petition, mailed 3/12/2007, granting conversion of Serial No. 09/754,842, filed 1/4/2001, to 60/331,362. The examiner respectfully assumes that the disclosure of the specifications of Serial No. 09/754,842 and the document "set bearing Express Mail Label EL 389 348 319 US", formerly known as Serial No. 60/331362, filed 1/4/2001, to be identical. If applicant disagrees with this assumption, applicant should so state on the record.

Applicants are submitting a petition to accept delayed priority claim. Applicants' attorney does not know now why the Notice of Non-Compliant Amendment was not responded to.

Applicants' Attorney has a practice of responding to such notices immediately, but in this case not such response was ever made.

Oath/Declaration

6. The oath or declaration is defective.

The Examiner Contends as follows:

> A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.
>
> The oath or declaration is defective because:
>
> Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).
>
> This objection to the oath/declaration is maintained because a new oath has not been filed.

Applicants are submitting a corrected oath/declaration.

Specification

The Examiner Contends as follows:

> 7. Applicants disclose nucleotide sequences in the drawings, particularly Figures 1 and 9, that must be identified by a SEQ ID number, pursuant to 37 CFR 1.821(d), which states: "Where the description or claims of a patent application discuss a sequence listing that is set forth in the 'Sequence Listing' in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application." The identification of the sequences by SEQ ID numbers may be in the Brief Description of the Figures; or in the drawings themselves.
>
> Because the aforementioned sequences are still not identified by SEQ ID No.s, the objection is maintained.

Applicants have added three sequences to the sequence listing for the AIPL1 rat protein, the AIP human protein and the AIP mouse protein of Figure 1. Applicants have also added a sequence for the 12 base deletion is Figure 9.

Withdrawn Claim Objections/Rejections

The Examiner stated as follows:

> 8. The following claim objections/rejections are withdrawn in view of applicant's arguments and amendments to the claims:

9. Claims 9-13 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for lack of written description.

10. Claims 9-13, 21-24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants acknowledge the withdrawal.

Claim Rejections - 35 USC § 102

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 9-13, 21-24 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sohocki et al., Nature Genetics, Jan. 1, 2000, Vol. 24, pp. 79-83.

The Examiner stated as follows:

> This rejection is maintained for the reasons of record, as set forth in the previous Office action. That rejection is copied below for the convenience of the reader.
>
> The claims, (as in claim 9 et seq.), are drawn to a method to determine if an animal has a retinal disease or has a propensity to pass a retinal disease to offspring, comprising the steps of: (A) extracting polynucleotide from a cell or sample; (B) determining if the polynucleotide contains a mutation in an AIPLI encoding or regulating region; and (C) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; and variations thereof.
>
> Also, the claims, (as in claim 21 et seq.), are drawn to methods for determining the presence of an APLI mutant in a patient sample, which comprises: (A) isolating polynucleotide extracted from the patient sample; (B) hybridizing a detectably labeled oligonucleotide to the polynucleotide isolated in step (b), the oligonucleotide having at its 3' end at least 15 nucleotides complementary to a wild type polynucleotide sequence having at least one mutation; (C) attempting to extend the oligonucleotide at its 3'-end; (D) ascertaining the presence or absence of a detectably labeled extended oligonucleotide; and (E) correlating the presence or absence of a detectably labeled extended oligonucleotide in step (e) with the presence or absence of a AIPL1 Trp278X mutation; and variations thereof.
>
> Also, the claims, (as in claim 27), are drawn to a method to determine if a cell or sample has an APL1 mutation comprising: (A) extracting polynucleotide from a cell; (B) amplifying polynucleotides which encode APL1; and (C) determining if the polynucleotide contains a Trp278X mutation; (D) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; and variations thereof.
>
> Sohocki et al., Nature Genetics, Jan. 1, 2000, Vol. 24, pp. 79-83, throughout the publication, and abstract disclose methods to determine if an animal has a retinal disease or has a propensity to pass a retinal disease to offspring, (see, e.g., Fig. 5), comprising the steps of: (A) extracting polynucleotide from a cell or sample, (e.g., p. 81, para 1); (B) determining if the polynucleotide contains a mutation in an AIPLI encoding or regulating region, (see e.g., Fig. 2, demonstrating mutant sequences, and p. 80, teaching elected mutation Trp278X); and (C) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring, (see, e.g., Fig. 5); and as in instant claims 9-13.
>
> Sohocki et al., throughout the publication and in the abstract, disclose methods for determining the presence of an APLI mutant in a patient sample, including members of a Pakistani family, LCA4 family, which comprises: (A) isolating polynucleotide extracted from the patient sample; (B) hybridizing a detectably labeled oligonucleotide to the polynucleotide isolated, (see, e.g., Fig. 1), the oligonucleotide having at its 3' end at least 15 nucleotides complementary to a wild type polynucleotide sequence having at least one mutation, (see, e.g., Figure 2); (C) attempting to extend the oligonucleotide at its 3'-end, (see, e.g., Fig. 1, Methods Section, p. 81, para 4-5, p. 82, para 2, p. 83, para 2); (D) ascertaining the presence or absence of a detectably labeled extended oligonucleotide; and (E) correlating the presence or absence of a detectably labeled extended oligonucleotide

with the presence or absence of a AIPL1 Trp278X mutation (see p. 80, para 1-6, Fig. 5); as in instant claims 21-24. Sohocki et al., in the abstract, teach taking a patient sample prior to isolation. Sohocki et al., at Fig. 1, and p. 81, para 6, teach amplification, hybridization, and fluorescence *in situ* hybridization (fluorochrome label), northern blot (radioisotope label), and digoxygenin *in situ* hybridization (enzyme label); as in instant claims 21-24.

Sohocki et al, throughout the publication, disclose method to determine if a cell or sample has an APL1 mutation comprising: (A) extracting polynucleotide from a cell; (B) amplifying polynucleotides which encode APL1; and (C) determining if the polynucleotide contains a Trp278X mutation; (D) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; as in instant claim 27.

Applicants are filing a continuation application to address this rejection and are abandoning this application, but request that the abandonment be postponed until the petition for a delayed claim of priority is ruled upon.

13. **Claims 9, 12, 13 and 27** are rejected under 35 U.S.C. 102(a) as being anticipated by Damji, et al., American Journal of Human Genetics, Oct. 2000, Vol. 67, No. 4 Supplement 2, pp. 382, Abstract 2142.

The Examiner stated as follows:

This rejection is maintained for the reasons of record, as set forth in the previous Office action. That rejection is copied below for the convenience of the reader.

Damji, et al., throughout the abstract, teach a method to determine if a human patient, (understood here to encompass broadly "an animal", as in the claim) has a retinal disease or has a propensity to pass a retinal disease to offspring, comprising the steps of: (A) extracting polynucleotide from a cell or sample; (B) determining if the polynucleotide contains a mutation in an AIPLI encoding or regulating region; and (C) correlating the presence of the mutation as an indication of a retinal disease or a propensity to pass a retinal disease to offspring; and wherein the determining is done via sequencing, (as in claim 12); and wherein the mutation is Trp278X, as in claim 13.

Applicants are filing a continuation application to address this rejection and are abandoning this application, but request that the abandonment be postponed until the petition for a delayed claim of priority is ruled upon.

The Commissioner is authorized to credit or debit deposit account no. 501518 as needed in filing this response.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000

Respectfully Submitted,

Date: **September 10, 2007**

Robert W. Strozier, Reg. No. 34,024